Unless otherwise noted, comments regarding each of these applications must be received not later than January 27, 1995.

A. Federal Reserve Bank of Cleveland (John J. Wixted, Jr., Vice President) 1455 East Sixth Street, Cleveland, Ohio 44101:

1. Citizens Independent Bancorp, Inc., Logan, Ohio; to become a bank holding company by acquiring 100 percent of the voting shares of The Citizens Bank of Logan, Logan, Ohio.

B. Federal Reserve Bank of Dallas (Genie D. Short, Vice President) 2200 North Pearl Street, Dallas, Texas 75201-2272:

1. Riverside Bancshares Inc., Logansport, Louisiana; to become a bank holding company by acquiring 89.46 percent of the voting shares of The Bank of Logansport, Logansport, Louisiana.

Board of Governors of the Federal Reserve System, December 27, 1994.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 94–32269 Filed 12–30–94; 8:45 am]

BILLING CODE 6210–01–F

Douglas J. Hanson; Change in Bank Control Notice

Acquisition of Shares of Banks or Bank Holding Companies

The notificant listed below has applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notice is available for immediate inspection at the Federal Reserve Bank indicated. Once the notice has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for the notice or to the offices of the Board of Governors. Comments must be received not later than January 17, 1995.

A. Federal Reserve Bank of Minneapolis (James M. Lyon, Vice President) 250 Marquette Avenue, Minneapolis, Minnesota 55480:

1. Douglas J. Hanson, Aurora, Colorado; to acquire an additional 4.32 percent, for a total of 25.01 percent, of the voting shares of Security State Bank Shares, Polson, Montana, and thereby indirectly acquire Security State Bank and Trust Company, Polson, Montana.

Board of Governors of the Federal Reserve System, December 27, 1994.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 94–32270 Filed 12–30–94; 8:45 am]

BILLING CODE 6210–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 94F–0440]

Sumitomo Chemical America, Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Sumitomo Chemical America, Inc., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of 2,2'-methylenebis(4-methyl-6-*tert*-butylphenol)monoacrylate as an antioxidant in acrylonitrile/butadiene/styrene copolymers intended for use in contact with food.

DATES: Written comments on the petitioner's environmental assessment by February 2, 1995.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 5B4443) has been filed by Sumitomo Chemical America, Inc., Specialty Chemicals, 345 Park Ave., New York City, NY 10154. The petition proposes to amend the food additive regulations in § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) to provide for the safe use of 2,2'-methylenebis(4-methyl-6-*tert*-butylphenol)monoacrylate as an antioxidant in acrylonitrile/butadiene/styrene copolymers complying with § 177.1020 (21 CFR 177.1020) intended for use in contact with food.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations promulgated under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Dockets Management Branch (address above) for public review and comment. Interested persons may, on or before (*insert date 30 days after date of publication in the* **Federal Register**), submit to the Dockets Management Branch (address above) written comments. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the **Federal Register**. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Dated: December 21, 1994.

Alan M. Rulis,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 94–32241 Filed 12–30–94; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 94E–0234]

Determination of Regulatory Review Period for Purposes of Patent Extension; Zemuron™ Injection; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting the notice that appeared in the **Federal Register** of September 15, 1994. The document announced FDA's determination of the regulatory review period for purposes of patent extension for Zeuron™ Injection (rocuronium bromide). The document was published with some errors. The document incorrectly stated: ''1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act became effective*: January 15, 1994. The applicant claims January 14, 1989, as

the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 15, 1994, which was 30 days after FDA receipt of the IND.'' The document should have stated: ''1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act became effective*: January 15, 1989. The applicant claims January 14, 1989, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 15, 1989, which was 30 days after FDA receipt of the IND.'' This document corrects those errors.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

In FR Doc. 94–22760, appearing on page 47341 in the **Federal Register** of September 15, 1994, the following corrections are made:

On page 47341, in the second column, in the third paragraph, in the fourth and ninth lines, ''January 15, 1994'' is corrected to read ''January 15, 1989''.

Dated: December 21, 1994.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 94–32242 Filed 12–30–94; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[HSQ–224–N]

CLIA Program: Approval of the Joint Commission on Accreditation of Healthcare Organizations As An Accrediting Organization

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: This notice announces the approval of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) as an accrediting organization for clinical laboratories under the Clinical Laboratory Improvement Amendments (CLIA) program. We have found that the accreditation process of this organization provides reasonable assurance that the laboratories accredited by it meet the conditions required by Federal law and regulations. Consequently, laboratories that voluntarily become accredited by JCAHO in lieu of receiving direct Federal oversight and continue to meet JCAHO requirements would meet the CLIA condition level requirements for laboratories and therefore are not subject to routine inspection by State survey agencies to determine their compliance with Federal requirements. They are, however, subject to validation and complaint investigation surveys.

EFFECTIVE DATE: This notice is effective for the period January 3, 1995 through January 3, 1997.

FOR FURTHER INFORMATION CONTACT: Tracey Mummert, (410) 597–5906.

SUPPLEMENTARY INFORMATION:

I. Background and Legislative Authority

On October 31, 1988, the Congress enacted the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100–578. CLIA replaced in its entirety section 353 of the Public Health Service Act (PHSA), as enacted by the Clinical Laboratories Improvement Act of 1967, and made every laboratory in the United States and its territories that tests human specimens for health reasons subject to the requirements established by HHS and Federal regulation whether or not it participates in the Medicare or Medicaid program and whether or not it tests specimens in interstate commerce. New section 353 requires HHS to establish certification requirements for any laboratory that performs tests on human specimens and certify through issuance of a certificate that those laboratories meet the certificate requirements established by HHS.

Section 6141 of the Omnibus Budget Reconciliation Act of 1989, Public Law 101–239, amended the Social Security Act (the Act) to require that laboratories participating in the Medicare program meet the certificate requirements of section 353 of the PHSA. Subject to specified exceptions, laboratories must have a current unrevoked and unsuspended certificate to be eligible for reimbursement in the Medicare or Medicaid programs or both. Laboratories that are accredited by an accreditation organization approved under section 353 of the PHSA will automatically be eligible for Medicare and Medicaid participation as long as they meet applicable State licensure requirements.

On February 28, 1992, we published several final rules in the **Federal Register** (57 FR 7002–7243) that implemented the amendments to section 353 of the PHSA. In a subsequent rule published January 19, 1993 (58 FR 5215), we added ''certificate for physician-performed microscopy procedures'' and amended some of the performance requirements previously published on February 28, 1992.

On July 31, 1992, we issued final rules (57 FR 33992), under authority found in section 353(e)(2) of the PHSA, that permit HCFA to approve a private, nonprofit organization as an accreditation organization for clinical laboratories under the CLIA program if that organization's requirements for its accredited laboratories are equal to or more stringent than the applicable CLIA program requirements established at 42 CFR part 493 of our regulations. Under § 493.501(d) of our regulations the approval period may not exceed six years.

In general, the accreditation organization must:

- Use inspectors qualified to evaluate laboratory performance and agree to inspect laboratories with the frequency determined by HHS;
- Apply standards and criteria that are equal to or more stringent than those condition level requirements established by HHS when taken as a whole;
- Provide reasonable assurance that these standards and criteria are continually met by its accredited laboratories;
- Provide HHS, within 30 days, with the name of any laboratory that has had its accreditation denied, suspended, withdrawn, limited, or revoked;
- Notify HHS at least 30 days prior to changing its standards; and
- If HHS withdraws its approval, notify its accredited laboratories of the withdrawal within 10 days of the withdrawal.

Along with requiring the promulgation of criteria for approving an accreditation body and for withdrawing such approval, CLIA requires HHS to perform an annual evaluation by inspecting a sufficient number of laboratories accredited by an approved accreditation organization as well as by any other means that HHS determines appropriate. Under section 353(o) of the PHSA, the Secretary may, by agreement, use the services or facilities of any other Federal, State or local public agency, or any private, nonprofit organization to conduct inspections of laboratories performing clinical testing on human specimens in the United States and its territories for the purpose of determining compliance with CLIA requirements.

II. Notice of Approval of JCAHO as an Accrediting Organization

In this notice, we approve JCAHO as an organization that may accredit laboratories for purposes of establishing their compliance with CLIA requirements for all specialty/subspecialty areas.